510(k) SUMMARY of Safety and Effectiveness
(Pursuant to 21 CFR 807.92)
September 10, 2010

K101097

SEP 22 2010

1 **Submitted By:**

BZ Medical Inc.
6611 SW Burlingame Ave
Portland, OR 97239

Contact Person:

Byron Zahler
President
503 244-7348

2 **Proprietary Name:** CalgaeSeal
Common Name: Topical Hemostasis Pad
Classification Name: Dressing, Wound, Drug

3 **Predicate Devices:**

a. DeRoyal Industries	Kalginate	K914779
b. TZ Medical	Neptune	K040208
c. Evolution Medical Tech.	Algiseal Pad	K091194

4 **Device Description:**

CalgaeSeal is calcium alginate packaged in a Tyvek and Mylar pouch and sterilized by gamma radiation to a 10^-6 SAL and used as a topical hemostasis pad.

CalgaeSeal can be used alone as a wound dressing. It may be used in conjunction with manual pressure or FDA cleared mechanical pressure devices to provide rapid control of bleeding and hemostasis at the skin surface.

5 **Device Intended Use:**

CalgaeSeal is used to promote the rapid control of bleeding and provide hemostasis for lacerations, abrasions, vascular access sites and following surgical incisions. It can be used to achieve hemostasis at the skin surface for arterial/venous catheterization/tubes, needle puncture, hemodialysis and in patients on anticoagulation therapy. May be used in conjunction with a facility approved, post-hemostasis site dressing.

6 **Technical Characteristics Summary:**

CalgaeSeal has the same technological characteristics as the predicates devices. Following is a summary of the technological characteristics of CalgaeSeal in comparison to those of the predicate devices.

Technical Characteristics	Predicated Devices Kalginate – K914779 Neptune – K040208 Algiseal Pad – K091194		CalgaeSeal – K101097
Material	Calcium Alginate		Identical
Chemical Composition	Mannuronate and Guluronate residues		Identical
Design	A sterile, nonwoven fabric pad made of heavy, dense denier calcium alginate fibers.		Identical
Function (A);	Absorbent – In moist wound, calcium Alginate changes to thick fibrous gel that provides a moist environment conductive to granulation tissue formation and epithelial growth.		Identical
Function (B):	Hemostasis – Concentrates coagulation components by absorbing the fluid components of blood.		Identical
Testing by DeRoyal in 510 (k) K914779:	Standard	Performance	
Biomaterials - skin irritation	ASTM F719	Pass	Identical
Contact Allergens	ASTM F720	Pass	Identical
Intracutaneous Injecting Extracts	ASTM F749	Pass	Identical
Systemic Injections of Extracts	ASTM F750	Pass	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BZ Medical, Inc.
% Mr. Byron Zahler
President
6611 SW Burlingame Avenue
Portland, Oregon 97239

SEP 22 2010

Re: K101097
Trade/Device Name: CalgaeSeal
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 10, 2010
Received: September 14, 2010

Dear Mr. Zahler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

K101097

510(k) Number (if known): **K101097**

Device Name: CalgaeSeal

SEP 22 2010

Indications for Use:

CalgaeSeal is used to promote the rapid control of bleeding and provide hemostasis for lacerations, abrasions, vascular access sites and following surgical incisions. It can be used to achieve hemostasis at the skin surface for arterial/venous catheterization/tubes, needle puncture, hemodialysis and in patients on anticoagulation therapy. May be used in conjunction with a facility approved, post-hemostasis site dressing.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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